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9	BEFORE THE MEDICAL BOARD OF CALIFORNIA DEPARTMENT OF CONSUMER AFFAIRS STATE OF CALIFORNIA		
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12		LG . N 000 0016 004670	
13	In the Matter of the Second Amended Accusation Against:	Case No. 800-2016-024673	
14	MAX RUDOLPH LEHFELDT, M.D.	SECOND AMENDED ACCUSATION	
15	Post Office Box 1526 South Pasadena, California 91031-1526		
16 17	Physician's and Surgeon's Certificate No. A 80511,	·	
18	Respondent.		
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20	<u>PARTIES</u>		
21	1. William Prasifka (Complainant) brings this Second Amended Accusation solely in his		
22	official capacity as the Executive Director of the Medical Board of California, Department of		
23	Consumer Affairs (Board).		
24	2. On September 18, 2002, the Board issued Physician's and Surgeon's Certificate		
25	Number A 80511 to Max Rudolph Lehfeldt, M.D. (Respondent). That Certificate was in full		
26	force and effect at all times relevant to the charges brought herein and will expire on May 31,		
27	2022, unless renewed.		
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# **JURISDICTION**

- 3. This Second Amended Accusation is brought before the Board, under the authority of the following laws. All statutory references are to the Business and Professions Code (Code) unless otherwise indicated.
- 4. Section 2227 of the Code provides that a licensee who is found guilty under the Medical Practice Act may have his or her license revoked, suspended for a period not to exceed one year, placed on probation and required to pay the costs of probation monitoring, or such other action taken in relation to discipline as the Board deems proper.
  - 5. Section 2234 of the Code states:

The board shall take action against any licensee who is charged with unprofessional conduct. In addition to other provisions of this article, unprofessional conduct includes, but is not limited to, the following:

- (a) Violating or attempting to violate, directly or indirectly, assisting in or abetting the violation of, or conspiring to violate any provision of this chapter.
  - (b) . . . .
- (c) Repeated negligent acts. To be repeated, there must be two or more negligent acts or omissions. An initial negligent act or omission followed by a separate and distinct departure from the applicable standard of care shall constitute repeated negligent acts.
- (1) An initial negligent diagnosis followed by an act or omission medically appropriate for that negligent diagnosis of the patient shall constitute a single negligent act.
- (2) When the standard of care requires a change in the diagnosis, act, or omission that constitutes the negligent act described in paragraph (1), including, but not limited to, a reevaluation of the diagnosis or a change in treatment, and the licensee's conduct departs from the applicable standard of care, each departure constitutes a separate and distinct breach of the standard of care.

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- 6. Section 2266 of the Code states: The failure of a physician and surgeon to maintain adequate and accurate records relating to the provision of services to their patients constitutes unprofessional conduct.
  - 7. Section 654.2 of the Code states:
  - (a) It is unlawful for any person licensed under this division or under any initiative act referred to in this division to charge, bill, or otherwise solicit payment from a patient on behalf of, or refer a patient to, an organization in which the licensee,

or the licensee's immediate family, has a significant beneficial interest, unless the licensee first discloses in writing to the patient, that there is such an interest and advises the patient that the patient may choose any organization for the purpose of obtaining the services ordered or requested by the licensee.

(b) The disclosure requirements of subdivision (a) may be met by posting a conspicuous sign in an area which is likely to be seen by all patients who use the facility or by providing those patients with a written disclosure statement. Where referrals, billings, or other solicitations are between licensees who contract with multispecialty clinics pursuant to subdivision (l) of Section 1206 of the Health and Safety Code or who conduct their practice as members of the same professional corporation or partnership, and the services are rendered on the same physical premises, or under the same professional corporation or partnership name, the requirements of subdivision (a) may be met by posting a conspicuous disclosure statement at a single location which is a common area or registration area or by providing those patients with a written disclosure statement.

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- (d) For the purposes of this section, the following terms have the following meanings:
- (1) "Immediate family" includes the spouse and children of the licensee, the parents of the licensee and licensee's spouse, and the spouses of the children of the licensee.
- (2) "Significant beneficial interest" means any financial interest that is equal to or greater than the lesser of the following:
  - (A) Five percent of the whole.
  - (B) Five thousand dollars (\$5,000).
- (3) A third-party payer includes any health care service plan, self-insured employee welfare benefit plan, disability insurer, nonprofit hospital service plan, or private group or indemnification insurance program.

A third party payer does not include a prepaid capitated plan licensed under the Knox-Keene Health Care Service Plan Act of 1975 or Chapter 11a (commencing with Section 11491) of Part 2 of Division 2 of the Insurance Code.

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8. California Code of Regulations, title 16, section 1364.11, states:

The amount of any fine to be levied by a board official shall take into consideration the factors listed in subdivision (b)(3) of Section 125.9 of the code and shall be within the range set forth below.

(a) In his or her discretion, a board official may issue a citation under Section 1364.10 for a violation of the provisions listed in this section.

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(10) Business and Professions Code Section 654.2.

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provided in response to a request for discovery.

13.	Patient A was referred to Respondent by the breast surgeon who ultimately performed
the prophyl	actic mastectomy to discuss breast reconstruction options.

- 14. Patient A, accompanied by her husband, presented to Respondent on January 12,
  2015. Respondent discussed with Patient A the option of a skin reducing breast reconstruction and a nipple-sparing breast reconstruction. During that consultation, Respondent informed
  Patient A that he used Seri Surgical Scaffold<sup>2</sup> for soft tissue support.
- 15. According to the patient and her husband, Respondent did not discuss the following: (1) the risks/benefits relating to options other than Seri Surgical Scaffold; (2) whether the Seri Surgical Scaffold for breast reconstruction had FDA approval, and (3) that Respondent had participated in Seri Surgical Scaffold studies sponsored by Allergan, the maker of Seri Surgical Scaffold.
- 16. Respondent's medical records, created on or about January 12, 2015, did not reflect that Respondent discussed with the patient alternative options to Seri Surgical Scaffold.
- 17. Respondent performed Patient A's breast reconstruction surgery on February 24,2015. Seri Surgical Scaffold was used in the procedure.
- 18. On May 13, 2015, Patient A underwent second stage breast reconstruction, at which time tissue expanders were removed and implants were placed. Respondent observed that some of the Seri Surgical Scaffold had not been incorporated into the patients' tissue, and Respondent debrided that material.
- 19. In approximately October 2016, in preparation for responding to a Board inquiry about his care of Patient A, Respondent added a notation to Patient A's chart indicating that he had discussed with Patient A the options of Seri Surgical Scaffold as opposed to Alloderm, a collagen scaffold made from cadaver tissue. Respondent did not date or initial this note. Respondent produced these records to the Board in response to a subpoena.
- 20. On or about March 5, 2018, the Board was advised of Respondent's October 2016 revision to his January 12, 2015 notes in the patient's medical record.

<sup>&</sup>lt;sup>2</sup> Seri Surgical Scaffold is a silk netting used in plastic surgery. It serves as a base for the body to regenerate tissue after medical procedures.

- 21. The standard of care requires that medical records reflect a complete, accurate and contemporaneous account of patient encounters. If errors or omissions are discovered in the medical record, corrections can be made, or additional information added. However, the corrections and/or addenda must be signed and dated to reflect that the "late entry" was made after the date of the patient encounter.
- 22. Respondent made alterations to Patient A's medical record approximately one year and nine months after the relevant patient encounter. His failure to sign and date the entry constitutes a departure from the standard of care.

# Patient B

- 23. Patient B, a 59-year-old female, presented at Respondent's office on May 11, 2016, for a body contouring consultation. She was seen by a physician assistant and referred to Respondent for further consultation.
- 24. On June 14, 2016, Respondent evaluated Patient B and found that she was not a good candidate for body contouring. He recommended abdominoplasty (tummy tuck) and liposuction to the flanks.
- 25. Respondent saw Patient B for a preoperative visit on July 28, 2016, and surgery was scheduled for August 8, 2016, at the Arcadia Outpatient Surgery Center.
- 26. Respondent performed abdominoplasty with liposuction to the flanks on August 8, 2016. A bupivacaine pain pump catheter was placed for post-operative pain relief. Norco, an opioid pain medication, was also provided post-surgery.
- 27. Patient B experienced nausea and vomiting when she arrived home after surgery. Upon contacting Respondent's office and leaving a message, she was advised to pick up a nausea medication from the pharmacy. Patient B still did not feel better and decided to stop taking her post-operative pain medications.
- 28. On August 13, 2018, Patient B's husband returned from taking his daughter to dance practice and discovered that Patient B was unresponsive. She was unable to be revived and expired. According to the autopsy report, the cause of death was community-acquired pneumonia with recent elective abdominoplasty as a contributing factor, possibly due to increased pain, and

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failure to inspire and expand the lungs.

- 29. The medical records for Patient B's visits of May 11, 2016, June 14, 2016, and July 28, 2016, were created by multiple authors without a clear indication of who wrote each note.
- 30. Respondent's medical records do not document post-surgical contacts with Patient B or her husband.
- 31. Respondent created personal notes after Patient B's death, which purport to document post-surgical contacts with Patient B and her husband. These personal notes were not included as part of Patient B's medical records. These personal notes include the following information:
- A. On August 9, 2016, Respondent's patient coordinator called the patient to follow up after surgery and left a message. No call-back from the patient was received.
- B. On August 11, 2016, a family member contacted Respondent's office stating that the patient suffered from nausea and was unable to "keep anything down." There were no complaints of chest pain, shortness of breath, or excessive abdominal pain. The note reflected that the message was conveyed to Respondent who requested that staff inquire as to whether the symptoms were related to pain medication or antibiotic administration. Staff called the patient's husband and clarified that the patient's symptoms were not related to taking other medications, and Respondent called in a prescription for Zofran, a medication used to prevent nausea and vomiting.
- 32. According to Respondent, Patient B was advised to transition to ibuprofen to manage her pain; however, Patient B's medical record does not reflect this recommendation.
- 33. Respondent failed to document post-surgery communications with Patient B and her family in Patient B's medical records and/or failed to clearly delineate the author of each note.

  These documentation failures constitute a departure from the standard of care.

#### Patient C

- 34. Patient C, a 37-year-old female, presented at Respondent's office in 2013 for bilateral breast reconstruction after planned prophylactic mastectomy. At the initial consultation, Patient C was noted to have asymmetric breasts that were ptotic.
  - 35. On January 21, 2014, Patient C had a preoperative visit, documented by Respondent's

physician's assistant, during which the risk and benefits of the procedure were discussed. Patient C signed a consent form on that date for "Bilateral Reconstruction with Tissue Expanders." The patient signed a second consent dated January 30, 2014, authorizing a "Bilateral Breast Reconstruction with Tissue Expanders and Seri Scaffold."

- 36. On February 4, 2014, Patient C underwent bilateral mastectomy performed by another physician. Respondent performed the breast reconstruction using Seri Surgical Scaffold to maintain the position of the inframammary fold, and attached it to the lower border of the pectoral muscle and chest wall to maintain the position of the tissue expander.
- 37. Post-operatively, Patient C was noted to have ecchymosis/vascular compromise of the right infero-medial mastectomy flap. On February 19 and March 3, 2014, she returned for debridement of the compromised right breast skin, and reclosure. Subsequently, turbid drainage was noted, and the right tissue expander and the Seri Surgical Scaffold was removed. These procedures were performed at Arcadia Outpatient Surgery Center. At the time of these procedures (as well as subsequent procedures), Respondent had an ownership interest in Arcadia Outpatient Surgery Center, but failed to disclose his ownership interest to Patient C.
- 38. On July 22, 2014, Patient C underwent delayed placement of a right breast tissue expander. On December 30, 2014, she underwent bilateral exchange of her tissue expanders for permanent silicone gel breast implants, and bilateral fat transfer to improve contours.
- 39. Post-operatively, Patient C healed without infection. On January 27, 2015, she was noted to have asymmetry. Patient C also expressed interest in larger implants. On April 7, 2015, Patient C had a preoperative visit, documented by Respondent's physician assistant, who noted that the plan is for "Seri Scaffold in right breast." Patient C signed an informed consent document, dated April 7, 2015, for "Bilateral Breast Implant Replacement Using Silicone Gel Implants and Placement of Strattice vs. Seri Scaffold in Right Breast."
- 40. On April 17, 2015, a second consent form was signed by Patient C for "removal/replacement-bilateral breast implants, placement of alloderm right breast." Patient C had this surgery on that date.
  - 41. Subsequently, Respondent performed additional procedures/surgeries on Patient C's

breasts, including latissimus dorsi myocutaneous flap plus implant reconstruction of the right breast and reinforcement of the lower-left breast with placement of a larger implant for symmetry. Patient C was last seen by Respondent on February 13, 2017.

- 42. Respondent's failure to disclose to Patient C that he was a paid consultant for Allergan, maker of the Seri Surgical Scaffold at the time, was a departure from the standard of care.
- 43. Respondent's failure to notify Patient C that his use of Seri Surgical Scaffold was an "off label" use was a departure from the standard of care.
- 44. Respondent's failure to accurately document Patient C's diagnosis on surgical scheduling forms and on disability forms (e.g., diagnosis was coded as M53.82 (cervical dorsopathy), which was incorrect) was a departure from the standard of care.
- 45. The consent form signed by Patient C on April 7, 2015 was for placement of "Strattice vs. Seri." The consent form signed at the surgery center was for Alloderm. Alloderm was used in Patient C's surgery. The placement of an incorrect consent form in Patient C's medical record was a departure from the standard of care.
- 46. Respondent's failure to disclose his financial interest in Arcadia Outpatient Surgery Center to Patient C was a departure from the standard of care.
- 47. Respondent committed repeated negligent acts in the care and treatment of Patient A, Patient B, and Patient C, and his license is subject to discipline.

#### SECOND CAUSE FOR DISCIPLINE

(Failure to Maintain Adequate and Accurate Records)

- 48. Respondent's license is subject to disciplinary action under Code section 2266 in that he failed to maintain adequate and accurate records. The circumstances are as follows:
  - 49. The allegations in the First Cause for Discipline are incorporated as if fully set forth.

### THIRD CAUSE FOR DISCIPLINE

(Failure to Disclose Financial Interest)

50. Respondent's license is subject to disciplinary action under Code section 654.2 and California Code of Regulations, title 16, section 1364.11, subdivision (10), in that he failed to